M-CLEAR WC- codeine phosphate, guaifenesin liquid R.A. McNeil Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

M-CLEAR WC

Drug Facts

Active ingredients (in each 5 mL teaspoonful)

Codeine Phosphate* 6.33 mg
*WARNING: May be habit-forming

Guaifenesin 100 mg

Purpose

Antitussive

Expectorant

Uses

temporarily relieves these symptoms due to the common cold:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.
- may cause or aggravate constipation
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	3 teaspoonfuls (15 mL) every 4 to 6 hours, not to exceed 18 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	1 1/2 teaspoonfuls (7.5 mL) every 4 to 6 hours not to exceed 9 teaspoonfuls in a 24 hour period
Children under 6 years of age:	Not recommended for use

Other information

Store at 59°-86°F (15°-30°C)

Inactive ingredients

citric acid, cotton candy flavor, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol

Questions? Comments?

Call 1-423-493-9170

Product Packaging

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Supplied in a tight, light-resistant container with a child-resistant cap.

This package not intended for dispensing to the patient.

Manufactured for: R.A. McNeil Company 1150 Latta Street Chattanooga, TN 37406-3738

Rev. 12/14



NDC 12830-0717-16

M-CLEAR WC

Antitussive • Expectorant

Sugar Free • Dye Free •
Alcohol Free

EACH 5 mL (1 TEASPOONFUL) CONTAINS:

Cotton Candy Flavor

ONE PINT (473 mL)

Mfg. for R.A. McNeil Company Chattanooga, TN 37406-3738

Rev. 12/14

Drug Facts

Lift Here

Active ingredients Purpose (in each 5 mL teaspoonful)

Codeine Phosphate* 6.33 mg Antitussive *WARNING: May be habit forming Guaifenesin 100 mg Expectorant

Uses temporarily relieves these symptoms due to the common cold:

- ■cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.
- may cause or aggravate constipation
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

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Drug Facts (continued)

Keep out of the reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:

Children 6 to under 12 years of age:

12 years of age:

Children 6 to under 11/2 teaspoonfuls (7.5 mL) every 4 to 6 hours, not to exceed 9 teaspoonfuls in a 24 hour period

Children under 6 Not recommended

for use

Other information

years of age:

Store at 59° - 86° F (15° - 30° C)

Inactive ingredients

citric acid, cotton candy flavor, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol

Questions? Comments?

Call 1-423-493-9170

M-CLEAR WC

codeine phosphate, guaifenesin liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12830-717	
Route of Administration	ORAL	DEA Schedule	CV	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII: UX6OWY2V7J)	CODEINE PHOS PHATE	6.33 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:12830-717- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2008		
2	NDC:12830-717- 30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2008		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/30/2008	

Labeler - R.A. McNeil Company (008305220)

Establishment				
Name	Address	ID/FEI	Business Operations	
Woodfield Pharmaceutical, LLC		079398730	manufacture(12830-717)	

Revised: 11/2021 R.A. McNeil Company